

# Tetraacetylethylenediamine (TAED) Interim Registration Review Decision Case Number 5105

## **April 2020**

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#### I. Introduction

This document is the Environmental Protection Agency's (EPA or the Agency) Interim Registration Review Decision (ID) for tetraacetylethylenediamine (TAED) (PC code 004115; Case 5105) and is being issued pursuant to 40 CFR sections 155.56 and 155.58. A registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may: 1) require new risk mitigation measures; 2) impose interim risk mitigation measures; 3) identify additional data or other information required to complete the review; and 4) include schedules for submitting the required data, conducting the new risk assessment, and completing the registration review. For further information on TAED, additional documents can be found in EPA's public docket (EPA-HQ-OPP-2013-0608) at <a href="https://www.regulations.gov">www.regulations.gov</a>.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandated the continuous review of existing pesticides. All pesticides distributed or sold in the United States generally must be registered by EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at <a href="http://www.epa.gov/pesticide-reevaluation">http://www.epa.gov/pesticide-reevaluation</a>. In 2006, the Agency implemented the registration review program pursuant to FIFRA section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

The Agency is issuing an interim registration review decision for TAED so that it can move forward with aspects of the registration review that are complete. The Agency has evaluated risks to listed species and is making a "no effect" finding for threatened and endangered species (hereafter referred to as listed species) and designated critical habitat and has therefore concluded that consultation with the Fish and Wildlife Services and the National Marine Fisheries Service (together, the Services) under the Endangered Species Act (ESA) § 7 is not required. See Section III.B. and Appendix A of this document and the *Endangered Species Effects Determination for Tetraacetylethylenediamine (TAED) Based on the Registration Review Draft Risk Assessment* memorandum for additional information. The Agency will complete endocrine screening for TAED, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), before completing registration review. See the TAED Proposed Interim

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<sup>&</sup>lt;sup>1</sup> U.S. EPA. April 2020. Endangered Species Effects Determination for Tetraacetylethylenediamine (TAED) Based on the Registration Review Draft Risk Assessment. Available in Docket # EPA-HQ-2013-0608 at www.regulations.gov.

Registration Review Decision Appendix B<sup>2</sup> for additional information about the endocrine screening for the registration review of TAED.

This document is organized in five sections: the *Introduction*, which includes a summary of TAED's registration review; *Use and Usage*, which describes how and why TAED is used and summarizes data on its use; *Scientific Assessments*, which summarizes EPA's risk assessments, updates or revisions to previous risk assessments, and provides broader context with a discussion of risk characterization; the *Interim Registration Review Decision*, which describes the regulatory rationale for EPA's interim registration review decision; and, lastly, the *Next Steps and Timeline* for completion of this registration review.

#### A. Summary of TAED Registration Review

Pursuant to 40 CFR section 155.50, EPA formally initiated registration review for the TAED chemical case (Case 5015; PC code 004115) in 2014. The following highlights significant events that have occurred during the registration review of TAED can be found in EPA's public docket, EPA-HQ-OPP-2013-0608, accessed at www.regulations.gov:

- March 2014 Publication of the *TAED Preliminary Work Plan (PWP)* was posted to the docket for a 60-day public comment period.
- October 2014 The *TAED Final Work Plan* (FWP) was posted to the docket. No comments were received on the *TAED Preliminary Work Plan (PWP)* during the 60-day public comment period
- June 2017 EPA issued a Generic Data Call-In (GDCI) for TAED (GDCI-004115-1429). All data requirements were either satisfied or waived.
- November 2019 The *TAED Human Health and Ecological Draft Risk Assessment* and *Tetraacetylethylenediamine (TAED) Proposed Interim Registration Review Decision (PID)* were concurrently posted to the docket for a 60-day public comment period.
- April 2020 EPA has completed the *TAED Interim Registration Review Decision* and is announcing its availability in the Federal Register in the docket EPA-HQ-OPP-2013-0608.

# **B.** Summary of Public Comments on the Draft Risk Assessment and Proposed Interim Registration Review Decision

No public comments were received regarding either the Draft Risk Assessment or Proposed Interim Decision for TAED.

<sup>&</sup>lt;sup>2</sup> https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0608-0007

#### II. Use and Usage

TAED (PC Code 004115, CAS #10543-57-4) is the only active ingredient within this case. Products containing TAED as an active ingredient are registered as biopesticides and antimicrobials. As an antimicrobial, products containing TAED function as disinfectants, sterilants, sporicides, bactericides, tuberculocidals, fungicides, and viricides on hard surface disinfectants in medical premises, agricultural premises, food handling establishments, and as a laundry additive for disinfection and sanitization in commercial, industrial, institutional premises and residential and/or public access premises. TAED products can be applied to non-porous food contact surfaces (e.g., countertops), non-food contact surfaces (e.g., floors or toilets) in addition to soft surfaces (e.g., carpets). Biopesticide products containing TAED are used as bactericides, fungicides, insecticides, and miticides in greenhouses, nurseries, and field uses such as strawberries, rice, nonbearing apple trees, nonbearing fruit trees, seeds, plugs and transplants of fruiting vegetables. The first products containing TAED were registered with the Agency in 2005.

Currently, there are four antimicrobial end-use products (EPs), which contain 0.12-61.6% TAED, and two manufacturing-use products (MPs), which contain 92-99.95% TAED. There are two active biopesticide registrations, one EP (containing 20% TAED) and one MP (containing 92% TAED).

The Agency recently reviewed three proposed new antimicrobial uses of TAED, including 1) wastewater treatment plants (WWTP) (tertiary treatment), 2) molluscicide for control of invasive mollusk species in industrial water intakes, and 3) hydraulic fracturing. These proposed uses, which are included as part of this registration review case, were evaluated as part of a Pesticide Registration Improvement Extension Act (PRIA) action to add three use sites to EPA Reg. No. 59825-1. In October 2019, these uses were approved for EPA Reg. No. 59825-1. Please reference *TAED Human Health and Ecological Draft Risk Assessment* in docket EPA-HQ-OPP-2019-0045 for additional information on these proposed uses.

Table 1. EPA Registered Antimicrobial Products Formulated with TAED

	EPA Registration Number	% AI	Company	Physical Form
1	1043-125	61.6	Steris Corporation	Water Soluble Packaging
2	5174-1	0.12	Devere Company,	Crystalline
			Inc.	
3	16930-5	11.9	Solids, Inc.	Soluble Concentrate/Solid
4	59825-1	92	The Lubrizol	Technical Chemical
			Corporation	
5	59825-5	99.95	The Lubrizol	Technical Chemical
			Corporation	

Table 2. EPA Registered Biopesticide Products Formulated with TAED

	EPA Registration Number	% AI	Company	Physical Form
1	59825-6	92	The Lubrizol Corporation	Technical Chemical
2	91853-3	20	Atoms F.D. Inc.	Crystalline

#### **III.** Scientific Assessments

#### A. Human Health Risk

A summary of the Agency's human health risk assessment is presented below in support of the registration review of TAED. The Agency used the most current science policies and risk assessment methodologies to prepare a draft risk assessment in support of the registration review of TAED. For detailed discussions of all aspects of the human health assessment, see the *TAED Human Health and Ecological Draft Risk Assessment*.<sup>3</sup>

#### 1. Risk Summary and Characterization

#### a. Antimicrobial Uses

The Agency has determined that there are no dietary, residential, occupational, aggregate, or cumulative risks of concern associated with antimicrobial products containing TAED.

TAED is a bleach activator and reacts with an oxygen activator (e.g., sodium percarbonate) and undergoes rapid hydrolysis under alkaline conditions to yield peroxyacetic acid (PAA, also known as peracetate), hydrogen peroxide, and diacetylethylenediamine (DAED). A short-lived intermediate, tri-acetyl ethylene diamine (triAED), is formed prior to DAED. The remaining acetyl groups on DAED cannot be further displaced by peroxide. TAED is essentially a carrier molecule for PAA, the active moiety. When formed, PAA and hydrogen peroxide are extremely powerful oxidizers and are the active components that will exhibit pesticidal activity. A determination has been made that there is a reasonable certainty of no harm to the U.S. population in general, and to infants and children, from the antimicrobial uses of TAED when label instructions are followed.

#### Dietary (Food + Water) Risks

Antimicrobial products containing TAED are not registered for uses with direct dietary exposure. Although use may result in indirect dietary food contact, based on chemical properties, PAA will impart antimicrobial action needed to disinfect or sanitize surfaces. The Agency anticipates negligible residues of TAED are available for transfer to food; thus, a quantitative chronic dietary exposure and risk assessment was not conducted.

<sup>&</sup>lt;sup>3</sup> The *TAED Human Health and Ecological Draft Risk Assessment* is located in the public docket EPA-HQ-2013-0608 at www.regulations.gov.

#### Residential Handler Risks:

Residential exposure exists when TAED is used as an active ingredient in disinfectant/sanitizers in residential kitchens, and as an antibacterial on countertops and other kitchen surfaces.

Inhalation exposure is anticipated. The estimated inhalation margin of exposure (MOE) is 38,000,000 exceeding the target MOE of 1000 and is not a risk of concern. Inhalation exposure can also occur to residents using laundry detergents containing TAED. The inhalation MOE for the wipe scenario is 14,000,000 and is not of concern (Target MOE = 1000).

There is also potential for dermal exposure for residential handlers applying TAED-containing antimicrobial products as well as post-application dermal exposure from textiles or floors treated with TAED. However, a dermal risk assessment is not required for TAED as effects from a 90-day dermal toxicity study performed in rats did not identify any adverse effects up to the highest dose tested of 2000 mg/kg/day.

#### Residential Post-Application Risks

While there is potential for oral exposure in children mouthing textiles laundered with TAED antimicrobial treated products and oral hand to mouth exposure to TAED treated floors, residues are expected to be negligible due to the chemistry of the product. TAED will rapidly form PAA that will have evaporated by the time any children play on the floor. A dermal risk assessment is not required for TAED as effects from a 90-day dermal toxicity study performed in rats did not identify any adverse effects up to the highest dose tested of 2000 mg/kg/day.

#### Aggregate Risks

A dietary assessment was not undertaken because no adverse effects could be attributed to a single administered oral dose; thus, no aggregate assessment is needed for TAED. An assessment of aggregate risk for the degradate PAA will be included in the peroxy compounds registration review case.<sup>4</sup>

#### **Cumulative Risks**

The Agency has not made a common mechanism of toxicity to humans finding as to TAED and any other substance and it does not appear to produce a toxic metabolite produced by other substances. Therefore, the Agency has not assumed that TAED has a common mechanism of toxicity with other substances for the purposes of this action.

#### Occupational Handler Risks

The Agency anticipates occupational handler inhalation exposure to the powder form of laundry detergents containing TAED when used in institutional and industrial laundry operations. For

<sup>&</sup>lt;sup>4</sup> The peroxy compounds registration review case can be found in docket EPA-HQ-OPP-2009-0456 at <a href="https://www.regulations.gov">www.regulations.gov</a>

handlers working in commercial laundry operations, the MOE is 4800, which is greater than the target MOE of 1000; therefore, not of concern. Potential occupational handler inhalation exposure is also anticipated when applicators are applying crystalline granules as an industrial floor sanitizer. With a target MOE of 1000, the Agency has calculated an MOE of 1,500,000, thus determining no risks of concern.

#### Occupational Post-Application Risks

Based on the use patterns there are no occupational post-application risks expected for antimicrobial uses of TAED.

#### i. Human Health Data Needs

The Agency does not anticipate calling in additional data for the registration review of TAED at this time for antimicrobial uses.

#### b. Biopesticide Uses

The Agency has determined that there are no dietary, residential, occupational, or aggregate, or cumulative risks of concern associated with the biopesticide products containing TAED as an active ingredient. Due to the chemical properties of TAED coupled with the current registered use patterns, there are no human health risks of concern. The Agency has considered human exposure from the biopesticide uses of TAED considering relevant safety factors from FQPA and FIFRA. A determination has been made that there is a reasonable certainty of no harm to the U.S. population in general, and to infants and children, from the biopesticide uses of TAED when label instructions are followed.<sup>5</sup>

#### Dietary (Food + Water) Risks

No quantifiable dietary exposure is expected from the biopesticide products containing TAED as an active ingredient. Biopesticide products containing TAED are used as an effective control of early season fungus and bacterial diseases and are to be applied well before any food commodity is harvested.

#### Residential Handler and Post-Application Exposures

Potential residential exposure from the biopesticide uses of TAED exist but is mitigated when used according to the label instructions. A residential exposure and risk assessment was conducted for the biopesticide uses of TAED at the time of registration due to the following reasons: 1) potential for dermal exposure for residential handlers to TAED and its metabolite DAED, 2) post application dermal and incidental oral exposure to DAED for adults and children including landscape areas at school and day care sites, and 3) the effects observed in the 90-day

<sup>&</sup>lt;sup>5</sup> Biopesticides Registration Action Document Tetraacetylethylenediamine (TAED) PC Code: 004115 (May 24, 2014)

oral, 90 day dermal and prenatal developmental toxicity studies. The results of the risk assessment indicate that the risk from exposure to TAED and DAED is negligible for residential handlers and post-application to adults and children when the biopesticide products are used according to label instructions.

#### Aggregate Risk

A dietary assessment was not undertaken because no adverse effects could be attributed to a single administered oral dose when the pesticide product containing TAED is used according to label instructions; thus, no aggregate assessment is needed. A risk assessment for the degradate PAA will be included in the peroxy compounds registration review case.

#### Cumulative Risks

The Agency has not made a common mechanism of toxicity to humans finding as to TAED and any other substance and it does not appear to produce a toxic metabolite produced by other substances. Therefore, the Agency has not assumed that TAED has a common mechanism of toxicity with other substances for this assessment.

#### Occupational Handler and Post-Application Exposures

Occupational handler exposure exists for the biopesticide products containing TAED as an active ingredient. Based on label instructions, exposure scenarios for mixer/loaders, applicators, flaggers, and field workers consisted of the following application methods: aerial, airblast, chemigation, groundboom, and field worker activities.

Any occupational exposure for mixer/loaders, applicators and flaggers is expected to be mitigated by the label-required personal protective equipment (PPE) including: coveralls, chemical resistant footwear plus socks, chemical resistant gloves, and protective eyewear. Due to potential dermal exposure of TAED and DAED to mixer/loaders, applicators and flaggers coupled with the effects observed in the 90-day dermal and prenatal developmental toxicity studies, an occupational exposure and risk assessment was not conducted.

BPPD uses for TAED consist of greenhouse, nursery, field applications to a range of agricultural commodities, as well as applications to turf and ornamentals. While inhalation points of departure have been identified, MOEs for occupational handlers in laundry facilities and industrial situations exceed the established LOC of 1000, indicating no risks of concern. Exposures from laundry facilities and industrial situations are expected to be higher than exposures from greenhouse, nursery, and field applications. Therefore, BPPD did not conduct a separate analysis, since the AD inhalation risk assessment represents the worst-case scenario for occupational exposure, and no risks of concern were found.

All MOEs calculated for mixers/loader, applicators, and flaggers using PPE required on the proposed EP label were greater than the Agency's Level of Concern (LOC) of 100 (10x for intraspecies variation and 10x for interspecies variation). MOEs greater than 100 do not exceed the Agency's LOC; therefore, risks are not to be considered to be of concern. For field workers, the calculated MOEs were greater than 400, which do not exceed the Agency's LOC of 100, for

orchard crops except for the post-application exposure scenario of thinning fruit for field workers. The MOEs for field workers that were thinning fruit were less than 400 until day two after treatment; however, based on label instructions, the product is only to be applied to orchard crops early in the season during bloom when no harvestable commodities are present (nonbearing fruit trees). Therefore, field workers who are expected to thin fruit will not be exposed to residues from the product until much later than day two after treatment. The Agency does not anticipate unreasonable adverse effects for field workers who are thinning fruit for orchard crops when the pesticide product is used according to label instructions. Based on the results of the post-application occupational risk assessment, unreasonable adverse effects for field workers post-application to DAED are not anticipated when the pesticide product is used according to label instructions.

#### i. Human Health Data Needs

The Agency does not anticipate calling in additional data for the registration review of TAED at this time for biopesticide uses.

#### 2. Human Incidents and Epidemiology

OPP's Incident Data System (IDS) includes reports of human health incidents from various sources, including mandatory FIFRA Section 6(a)(2) reports from registrants, other federal and state health and environmental agencies, and individual consumers. Since 1992, OPP has compiled these reports in IDS. A search of the IDS in February 2020 revealed no reported human incidents associated with antimicrobial and biopesticide uses of TAED.

#### 3. Food Tolerances/Food and Drug Administration (FDA) Food Contact Notifications

Since the dietary exposure to TAED is determined to be negligible, a dietary risk assessment is not necessary. The FDA has issued a Food Contact notification for TAED when used as a bleaching agent in the manufacture of food-contact paper and paperboard products. Table 1 lists the Food Contact Notifications and limits/specifications.

Table 3: Summai	ry of Effective Food	Contact Substance l	<b>Notifications</b>
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FCN No.	Manufacturer	Chemical	Intended Use	Limit
1331	Warwick International, Ltd	Bis-1,2-((N,N-diacetyl)amino)ethane (CAS Reg. No. 10543-57-4)	As a bleaching agent in the manufacture of food-contact paper and paperboard products complying with 21 CFR	The FCS will be used at levels not to exceed 0.4 weight percent bis-1,2-((N,N-diacetyl)amino)ethane in pulp (on a dry weight basis). The finished food-contact articles may be used in contact with all types of food, and under Conditions of Use D through H as described in Table 2.

<sup>&</sup>lt;sup>1</sup> https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=FCN&id=133

In light of available toxicity and exposure data, the Agency concluded that there was a reasonable certainty that no harm would result to the U.S. population from aggregate exposure to

residues of TAED and its metabolite DAED. Therefore, the Agency established a tolerance exemption for residues of the active ingredient and its metabolite under the United States Federal Food, Drug, and Cosmetic Act (FFDCA) Section 408. This exemption is listed in Table 2 and is found in 40 CFR § 180.1327. The tolerance exemption appropriately covers DAED, the metabolite of TAED.

**Table 4: Summary of EPA Tolerance Exemptions** 

40 CFR Section	Exemption	Use	Chemical	Maximum Residue Level
180.1327 <sup>1</sup>	diacetylethylenediamine (DAED), in or on	and bactericide on	and its metabolite	No limits given.

<sup>&</sup>lt;sup>1</sup>https://www.ecfr.gov/cgi-bin/text-idx?SID=3cbf2ae5f3f00f9bf774069c33a7d621&mc=true&node=se40.26.180 11327&rgn=div8

Due to indirect dietary exposures from food contact uses for TAED antimicrobial products, a tolerance or exemption from the requirement of a tolerance must be established under FFDCA Section 408. The Agency will use its FFDCA rulemaking authority to pursue tolerance changes.

#### **B.** Ecological Risks

A summary of the Agency's ecological risk assessment is presented below. The Agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of TAED. For additional details on the ecological assessment for TAED, see the *TAED Human Health and Ecological Draft Risk Assessment*.<sup>6</sup>

Based on current use patterns, environmental exposure to TAED and its degradates is expected to be low and to occur at concentrations well below those that would result in any adverse effects to terrestrial or aquatic organisms. Therefore, the use of this chemical will not cause adverse effects to non-target organisms, including honeybees. The Agency has made a "no effect" determination for the registered uses of TAED under the ESA. See Appendix A of this document and the ESA memorandum<sup>7</sup> for more details.

#### Aquatic and Terrestrial Organisms

TAED and DAED have been determined to be practically nontoxic to aquatic and terrestrial

<sup>&</sup>lt;sup>6</sup> The *TAED Human Health and Ecological Draft Risk Assessment* is located in the public docket EPA-HQ-2013-0608 at <a href="www.regulations.gov">www.regulations.gov</a>.

<sup>&</sup>lt;sup>7</sup> The Endangered Species Effects Determination for Tetraacetylethylenediamine (TAED) Based on the Registration Review Draft Risk Assessment memorandum is located in the public docket EPA-HQ-2013-0608 at www.regulations.gov.

organisms. Nontarget terrestrial insects (honeybee) data were not required due to lack of exposure based on the TAED use patterns. Therefore, the Agency determined that no pollinator exposure and effects data are necessary to make a Final Registration Review Decision for TAED.

#### 1. Risk Summary and Characterization

#### a. Antimicrobial Uses

While ecological exposure may potentially occur, due to TAED's chemical properties as well as registered use patterns, no ecological risks of concern exist. All currently registered antimicrobial uses of TAED products enter a WWTP prior to discharge into the environment. TAED will break down into its degradate DAED as PAA reacts with organic matter. Thus, any exposure to aquatic organisms is expected to be to DAED. The ultimate biodegradation products of TAED and DAED are water, nitrate, and ammonia. These are all naturally found in the environment and are readily metabolized by microorganisms.

Environmental exposures and corresponding risks from registered antimicrobial uses for TAED products are expected to be negligible because (1) the nature of the use sites indicate that TAED and its degradate will enter a WWTP, (2) its use in these sites would be widespread geographically and vary temporally during the year, and  $(3) \ge 95\%$  TAED will degrade within the WWTP prior to discharge, any PAA will degrade upon contact with organic matter and most DAED will undergo biodegradation before release.

#### b. Biopesticide Uses

No ecological risk was determined from the biopesticide uses of TAED. TAED is practically nontoxic to fish, aquatic invertebrates, aquatic plants, and birds and minimal exposure is expected to either the parent or the degradate. Therefore, no updated environmental risk assessment was performed as part of this registration review. The ecological database for the biopesticide uses of TAED is considered complete.

#### 2. Ecological Incidents

OPP's Incident Data System (IDS) includes reports of ecological incidents from various sources, including mandatory FIFRA Section 6(a)(2) reports from registrants, other federal and state health and environmental agencies, and individual consumers. Since 1992, OPP has compiled these reports in IDS. Based on a February 2020 search of the IDS, no ecological incidents have been reported for TAED uses.

#### 3. Ecological and Environmental Fate Data Gaps

The submitted ecological and environmental fate data are sufficient to complete a risk assessment for the TAED case. Therefore, no data gaps were identified and no additional ecotoxicity studies are required for this registration review.

#### IV. Interim Registration Review Decision

#### A. Risk Mitigation and Regulatory Rationale

In accordance with 40 CFR sections 155.56 and 155.58, the Agency is issuing the *TAED Interim Registration Review Decision*. Except for the Endocrine Disruptor Screening Program (EDSP), the Agency has made the following Interim Registration Review Decision: (1) no additional data are needed at this time, and (2) changes to the affected registrations and their labeling are not needed at this time.

In this ID, the Agency is making no human health or environmental safety findings associated with the EDSP screening of TAED. The Agency has made a "no effect" determination for the registered uses of TAED under the ESA. See Appendix A and the ESA memorandum for additional details on the endangered species determination. The Agency's final registration review decision for TAED will be dependent upon the result of the Agency's EDSP FFDCA § 408(p) determination.

#### 1. Risk Mitigation Measures

The *TAED Interim Registration Review Decision (ID)* requires no risk mitigation measures because no human health or ecological risks of concern were identified in the Draft Risk Assessments for TAED. The PID for TAED was released for a 60-day public comment period on November 18, 2019. EPA did not receive any public comments in response to the PID for TAED. Therefore, other than the "no effects" ESA determination, no additional changes have been made to the risk assessment, and risk mitigation measures are not needed at this time.

#### **B.** Data Requirements

The Agency does not anticipate calling-in additional data for the TAED registration review at this time.

#### C. Antimicrobial Tolerance Actions

Due to indirect dietary exposures from food contact uses for TAED antimicrobial products, a tolerance or exemption from the requirement of a tolerance must be established under The United States Federal Food, Drug, and Cosmetic Act (FFDCA) Section 408. The Agency will use its FFDCA rulemaking authority to pursue tolerance changes.

<sup>&</sup>lt;sup>8</sup> The Endangered Species Effects Determination for Tetraacetylethylenediamine (TAED) Based on the Registration Review Draft Risk Assessment memorandum is located in the public docket EPA-HQ-2013-0608 at www.regulations.gov.

#### V. Next Steps and Timeline

#### A. Interim Registration Review Decision

In accordance with 40 CFR Sections 155.56 and 155.58, the Agency is issuing the *TAED Interim Registration Review Decision*. A Federal Register Notice will announce the availability of this Interim Registration Review Decision. In this ID, the Agency has made a "no effect" determination for the registered uses of TAED. See Section III.C., Appendix A, and the ESA memorandum<sup>9</sup> for additional details on the endangered species assessment. The Agency is making no human health or environmental safety findings associated with the EDSP of TAED. See Appendix B of the PID for additional information. The Agency's final registration review decision for TAED will be dependent upon the result of the EDSP FFDCA section 408(p) determination.

#### **B.** Implementation of Mitigation Measures

There are no risk mitigation measures or label amendments required by this Interim Decision.

<sup>&</sup>lt;sup>9</sup> The Endangered Species Effects Determination for Tetraacetylethylenediamine (TAED) Based on the Registration Review Draft Risk Assessment memorandum is located in the public docket EPA-HQ-2013-0608 at <a href="https://www.regulations.gov">www.regulations.gov</a>.

#### **Appendix A: Endangered Species Assessment**

There is no reasonable expectation for any registered use of TAED to cause direct or indirect adverse effects to threatened and endangered species. No adverse modification of critical habitat is expected from the use of TAED. Based on current use patterns, environmental exposure to TAED and its degradates is expected to be low and to occur at concentrations well below those that would result in any adverse effects to terrestrial or aquatic organisms. See the *Endangered Species Effects Determination for Tetraacetylethylenediamine (TAED) Based on the Registration Review Draft Risk Assessment* located in the docket for this TAED case for more information. The EPA has made a "no effect" determination under the ESA for all listed species and designated critical habitat for such species and has therefore concluded that consultation with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service under ESA § 7(a)(2) is not required.